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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities;
Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Patient-Reported Health Information Technology and Workflow." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the Federal Register on February 13th, 2013 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by (insert date 30 days after date of publication).

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by email at OIRASubmission@omb.eop.gov (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at dorislefkowitz@AHRO.hhs.gov.

SUPPLEMENTARY INFORMATION:
Proposed Project

Patient-Reported Health Information Technology and Workflow

Health IT can improve quality of care by arraying relevant information, displaying clinical guidelines, highlighting test values of concern, calculating medication doses, and supporting clinical decisionmaking in many ways (Chaudhry et al., 2006). Successful health IT implementation requires careful attention to the workflow of clinicians and others involved in care delivery. However, few studies have examined how health IT can change workflow in ambulatory physician practices. Further, in most studies that address health IT in ambulatory settings, workflow is not the main focus of the research (Unertl, Weinger, Johnson et al., 2009, Carayon, Karsh, Cartmill et al., 2010a). The health IT literature has not focused on sociotechnical factors, such as patient or provider characteristics, physical environment and layout; technical training

and support; functionality and usability of health IT; worker roles, staff workload, stress, and job satisfaction; and communication flows. Important work that does address such factors comes mainly from inpatient settings, or from other countries where the health care system is quite different than in the U.S. (Tjora and Scambler, 2009; Ammenwerth, filer, and Mahler, 2006; Niazkhani, Pirnejad, de Bont et al., 2008; Niazkhani, Pirnejad, Berg et al., 2009). Although many of these studies have concluded that changes in workflow occur when implementing different health IT applications, few studies have actually examined how workflow changes.

In recent years there has been an increase in the use of health IT to capture patient reporting of medical histories, symptoms, results of self-testing (e.g., blood glucose levels, blood pressure), weight questions and concerns, over-the-counter medication use, and other information that patients need to share with their care providers. Health IT can elicit such information from patients, and help incorporate it into the flow of information within a physician's practice so that the information is detailed, actionable, timely, and can be used to meet patients' treatment goals. Gathering and integrating information from patients using health IT can include:

- Patient portals, sometimes referred to as (electronic) personal health records or PHRs, allow patients to view portions of their medical records (e.g., laboratory test results), and support other health-related tasks such as making appointments or requesting medication refills. Some patient portal applications exist as standalone Web sites; other portal applications are integrated into an existing electronic health record [ERR] system;
- Secure messaging with patients (use of secure e-mail between patients and clinicians, typically using the secure messaging functionality in the ERR and/or patient portal) (Byrne, Elliott, and Firek, 2009; Bergmo, Kummervold, Gammon et al., 2005); and
- E-forms (surveys that are administered using computerized media [e.g., tablets, laptops] to collect information from patients using pre-formatted forms before or during patient visits).

The use of patient-reported information is not yet widely integrated into health IT. This project will fill the gaps in the current literature by exploring the influence of sociotechnical factors - for clinicians and their office staff, and for patients - in capturing and using patient-reported information in ambulatory health IT systems and associated workflows. The goal of the project is to answer the following research questions:

- How does the use of health IT to capture and use patient-reported information support or hinder the workflow from the viewpoints of clinicians, office staff, and patients?
- How does the sociotechnical context influence workflow related to the capture and use of patient-reported information?
- How do practices redesign their workflow to incorporate the capture and use of patient-reported information?

The study will consist of rigorous mixed-methods case studies of six ambulatory care physician practices including three small practices (1-4 physicians and the other clinicians and office staff in their practices) and three medium-sized practices (5-10 physicians, and the other clinicians and office staff in their

practices). These case studies will be conducted during multiday (3 to 4 days) site visits to collect information for this exploratory research. The multiple case study research approach of Eisenhardt and colleagues (Brown & Eisenhardt, 1997; Eisenhardt, 1989) will guide data collection and data analysis, to elucidate health IT workflows and important sociotechnical factors (for patients, clinicians, and office staff) in the capture and use of patient-reported information.

A focus of the case studies will be to identify current workflows related to patient-reported information, and determine the work system factors that influence workflows (barriers and facilitators). In particular, data collected from the six practices will help identify bottlenecks and sources of delay, unnecessary steps or duplication, rework to correct errors or inconsistencies, role ambiguity, missing information, and lack of data quality controls or reconciliation of inconsistencies. The focus is not on the content of information reported by patients, or how it alters clinicians' diagnostic or treatment decisions. Rather, the focus is on the workflows required to capture, process, and make use of information that patients report to their care providers.

This study is being conducted by AHRQ through its contractor, Abt Associates Inc., and subcontractors University of Wisconsin-Madison and University of Alabama-Birmingham, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to health care technologies and the quality, effectiveness, efficiency, appropriateness and value of health care services including quality measurement and improvement. 42 U.S.C. 299a(a)(1), (2) and (5).

Method of Collection

To achieve the goal of this project the following activities will be conducted at each of six participating ambulatory physician practices (referred to herein as 'study sites'):

- 1) Preliminary Conference Call: The Practice Manager (the individual in each practice who manages day-to-day operations) and the Physician Leader (the physician in each practice who is most knowledgeable about health IT and health IT implementation) will be asked to participate in a preliminary conference call to learn about the study site and what will be expected of their practice as a study site. This call will last approximately one hour and will be completed by up to 2 participants per site for a total of up to 12 participants across sites.
- 2) Pre-Visit Questionnaire: The Practice Manager will be asked to complete a brief questionnaire prior to the site visit, describing the practice size, health IT installed, patient population served, and other general contextual information about the practice and use of health IT. The Pre-Visit Questionnaire will take approximately one hour to complete and will be completed by up to one respondent per study site.
- 3) Practice Tour: Each of the six site visits will begin with a one-hour tour of the practice and discussion with the Practice Manager to observe the physical layout and computer work stations, clarify the purpose of the study and the site visit, and clarify information from the Pre-Visit Questionnaire.
- 4) Interviews with Practice Manager and Physician Leader: Following the tour at each study site, the Practice Manager and Physician Leader will be asked to

participate in a one hour interview. The interview with the Practice Manager will focus on the sociotechnical context of the practice, with an emphasis on the social context of the practice. The interview with the Physician Leader will also focus on the sociotechnical context of the practice, and, in particular, the technical aspects of clinicians using the health IT system. The focus will be on the workflow across the practice, not the workflow of these two individuals. This information will be used to create the basic outline or structure of a Workflow Process Map(s), a diagram that shows the temporal sequencing of tasks in relation to other work system elements (person, organization, environment, and tools and technologies). It will also be used to begin to identify potential variation or flexibility in individuals' workflows, and provide context regarding multiple IT systems that may be in use in the practice. The information obtained from these interviews will be augmented by observation of workflows in the practice and interviews with others in the practice, as described in #5 and #6.

5) Observations of Clinicians and Office Staff: Researchers will observe between 8 to 20 clinicians (including physicians, nurse practitioners, physician assistants, nurses, medical assistants, and ancillary staff) and between 3 to 7 office staff (including the front desk receptionist, IT staff, clerks, and other non-clinical staff) per study site, depending on site size for a total of up to 84 clinicians and up to 30 office staff observations across the study sites. Observations will take place as clinicians and office staff work to elicit, integrate and work with patient-reported information. Each clinician will be observed for up to two hours and each office staff person will be observed for up to 30 minutes. These observations periods are different because clinicians' work is more complex and varies more from one patient to the next, while office staff work varies less. Observations will focus on processes, bottlenecks, facilitators, workarounds, and points in the workflow when paper information supplements electronic information. Observations of both clinicians and office staff will be recorded on the Observation Form. The observations will be used to create a detailed Workflow Process Map(s). This data collection will not burden the clinic staff and is not included in the burden estimates in Exhibit 1.

6) Interviews with Clinicians and Office Staff: Following observations of the workflow, each clinician and office staff person who was observed will be interviewed for up to one hour, for a total of up to 84 clinicians and up to 30 office staff interviews. If there are more clinicians or office staff than can be interviewed during the site visit, those with the most extensive experience with patient-reported information will be selected for interviews. These interviews will include discussion about the sociotechnical context, the workflow observed (see above), facilitators and barriers to capturing and using patient-reported information, and whether there are uncommon workflow patterns that arise occasionally but were not observed. Unlike the interviews with the Physician Leader and Practice Manager, these interviews will focus on the workflow of each individual, not the workflow across the entire practice. The same interview guide will be used for both clinician and office staff interviews.

7) Survey of Clinicians and Office Staff: All clinicians and office staff in the six study sites will be invited to respond to a survey. Although there may not be sufficient time on site to observe and interview every clinician and office staff person in the medium-sized practices, all of them will be asked to complete the survey questionnaire. Therefore, the number of survey respondents is greater than the number of observed and interviewed individuals. Up to 11 surveys will be completed at each small-sized study site and up to 35 surveys will be completed at each medium-sized study site, for a total of up to 138

respondents across the six sites. The surveys will be used to collect data regarding attitudes about and perceptions of the health IT workflows staff engage in related to patient-reported information and the impact of health IT on workload, stress, and job satisfaction, because workflow can impact workload and job satisfaction which have been shown to impact quality of care. The survey will also be used to collect data on barriers and facilitators associated with capturing and using patient-reported information.

8) Patient Interviews: Patients will be interviewed to the understand the workflow of entering or reporting information from the patient's perspective; the extent and adequacy of training or instruction patients received in using the health IT; attitudes about the time it takes to report information; and whether there are challenges, barriers, facilitators, or workarounds commonly used by patients as they report information requested by their cue providers. Five patients will be interviewed at each small practice and up to seven at each medium-sized practice, for a total of up to 36 across the six study sites. More patients will be interviewed in the medium-sized practices because there are more clinicians in these practices, and each may have different patterns of interacting with their patients. Interviewing more patients will enhance the ability to capture information about variation in the clinician-patient information sharing and interaction. These interviews will help researchers understand the range of patient experiences.

9) Post-Visit Follow-up to Review the Workflow Process Map(s): Following each site visit, researchers will complete the Workflow Process Map(s) for the study-site and send it to the Practice Manager and Physician Leader, requesting confirmation that the understanding of their workflows is correct.

The lessons learned from this research may be used in a variety of ways:

- 1) To identify additional workflow components that ambulatory practices should consider when implementing health IT to capture and use patient-reported information;
- 2) To identify issues relevant to best practice guidelines for health IT implementation;
- 3) To identify issues for consideration in the design and evaluation of other patient-centered health IT tools.

The study findings will be widely disseminated to health IT researchers and implementers via AHRQ's National Resource Center for Health IT Web site. The study will enhance the existing knowledge about sociotechnical factors that impact health IT workflow, and how small and medium-sized ambulatory practices employ health IT to capture and use patient-reported information as they redesign their workflow to deliver patient-centered care.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annual burden hours for the respondents' time to participate in this research. The Preliminary Conference Call with each site will involve two people, the Practice Manager and the Physician Leader, and will require up to one hour per site. A total of 12 people across the six study sites will be involved.

The Pre-Visit Questionnaire and the Practice Tour will be completed by the Practice Manager at each site and will require up to one hour each. The Practice

Manager and the Physician Leader at each site (12 individuals in total across the 6 sites) will be separately interviewed to gather in depth information about the sociotechnical context of the practice. The interviews will each take up to one hour to complete.

Interviews with Clinicians and Office Staff will be completed with a maximum of 114 clinicians and office staff across the six study sites, and each interview will last up to one hour. A maximum of 138 clinicians and office staff combined (up to 11 for each of three small-sized sites and 35 for each of 3 medium-sized sites) will be asked to complete the clinician and office staff survey, which will take approximately 15 minutes for each respondent to complete.

Up to 36 patients will be interviewed (5 in each of the small sites and up to 7 in each of the medium-sized sites). Each interview will take no more than 30 minutes to complete. A total of 12 persons (the Practice Manager and the Physician Leader at each site) will be involved in the Post-Visit Follow-up to Review the Workflow Process Map(s), which will take one hour. The total annual burden hours, is estimated to be 215 hours.

Exhibit 2 shows the estimated annual cost burden associated with the study sites' time to participate in the research. The total annual cost burden is estimated to be \$10,815.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Preliminary Conference Call	12	1	1	12
Pre-Visit Questionnaire	6	1	1	6
Practice Tour	6	1	1	6
Interviews with Practice Manager and Physician Leader	12	1	1	12
Interviews with Clinicians and Office Staff	114	1	1	114
Survey of Clinicians and Office Staff	138	1	15/60	35
Patient Interviews	36	1	30/60	18
Post Visit Follow-up to Review the Workflow Process Map(s)	12	1	1	12
Total	336	N/A	N/A	215

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Preliminary Conference Call	12	12	\$67.15\	\$806
Pre-Visit Questionnaire	6	6	\$46.17\	\$277
Practice Tour	6	6	\$46.17\	\$277
Interviews with Practice Manager and Physician Leader	12	12	\$67.15\	\$806

Interviews with Clinicians and Office Staff	114	114	\$50.97\c\	\$5,811
Survey of Clinicians and Office Staff	138	35	\$46.89	\$1,641
Patient Interviews	36	18	\$21.74\c\	\$391
Review of the Workflow Process Map(s)	12	12	\$67.15\c\	\$806
Total	336	215	N/A	\$10,815

* Based upon the mean of the average hourly wages, National Compensation Survey: Occupational wages in the United States May 2011, "U.S. Department of Labor, Bureau of Labor Statistics.

\a\ the average wage for Practice Managers (\$46.17 per hour) and Physician Leaders (\$88.12 per hour) [\$88.12 reflects the average for Family and General Practitioners (\$85.26 per hour) and Internists, General (\$90.97 per hour)].

\b\ the average U.S. wage for Practice Managers is \$46.17 per hour.

\c\ the weighted average wage for physicians (\$88.12 per hour) [\$88.12 reflects the average for Family and General Practitioners (\$85.26 per hour) and Internists, General (\$90.97 per hour)], nurse practitioners and physician assistants (\$41.63 per hour) [\$41.63 reflects the average for Physician Assistants (\$43.01 per hour) and Health Diagnosing and Treating Practitioners, All (\$40.24 per hour)], nurses (\$33.23 per hour), and Office Staff (\$17.94) [reflects the average for Receptionists and Information Clerks (\$12.85 per hour), Office and Administration Support Workers, All Other (\$16.07 per hour), and Computer Support Specialists (\$24.91 per hour)].

\d\ the weighted average wage for physicians (\$88.12), nurse practitioners and physician assistants (\$41.63), nurses (\$33.23) and office staff (\$17.94).

\e\ the average U.S. hourly wage (\$21.74).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: April 15, 2013

Carolyn M. Clancy,
Director